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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/350,899	07/12/1999	KOUICHI TSUJI	029650-080	8923

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EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 04/22/2004

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/350,899

Applicant(s)

TSUJI ET AL.

Examiner

Karen A Canella

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 10-12 and 15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 11 is/are allowed.
- 6) ☐ Claim(s) 12 and 15 is/are rejected.
- 7) ☐ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Art Unit: 1642

DETAILED ACTION

1. Claims 10 and 11 have been amended. Claims 10-12 and 15 are pending and under consideration.
2. Sections of Title 35, US Code, not found in this action can be found in a previous action.
3. Claim 10 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 11. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 11 differs from claim 10 only in the enumeration of the lectins to which the glycoprotein binds or does not bind. The specification teaches that the characteristics of the claimed glycoprotein antigen are reactivity with MAA lectin and PNA lectin, but no reactivity with GNA lectin, SNA lectin and DSA lectin. This reactivity would be inherent in the glycoprotein of claim 11, and the specification is not enabling for a genus of glycoproteins having only one of the claimed reactivities to MAA lectin or PNA lectin, or lacking reactivity to only one of GNA lectin, SNA lectin or DSA lectin. Because the specification is enabling for only one glycoprotein antigen having the recited reactivities with the MAA, PNA, GNA, SNA and DSA lectins, claim 10 has the same scope as claim 11.
4. Claims 12 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 recites "determining whether said sample contains human adenocarcinoma cells based on the binding or absence of binding of the glycoprotein antigen in said sample to said monoclonal antibody" and as such fails relate the binding of the antibody fragment to the diagnosis of human adenocarcinoma as set forth in the claim objective..

Art Unit: 1642

5. The rejection of claim 12 [indicated as claim 11 in the previous Office action] under 35 U.S.C. 101 as claiming the same invention as that of claim 4 of prior U.S. Patent No. 6,015,680 is maintained for reasons of record. Claim 4 of '680 is as follows:

4. An immunoassay method for diagnosis of human pulmonary adenocarcinoma which comprises contacting a sample of a subject suspected of having human pulmonary adenocarcinoma with a monoclonal antibody or fragment according to claim 1 and correlating whether the subject has pulmonary adenocarcinoma based on the binding or absence of binding of said antibody to any human pulmonary adenocarcinoma antigen contained in said sample, wherein said human pulmonary adenocarcinoma antigen is the antigen specifically bound by said monoclonal antibody or fragment thereof.

It is noted that claim 4 of '680 is drawn to the diagnosis of pulmonary carcinoma and the instant claim is drawn to the diagnosis of lung carcinoma. Stedman's Medical Dictionary (27 Edition 2000) defines pulmonary as:

Relating to the lungs, to the pulmonary artery, or to the aperture leading from the right v entricle into the pulmonary artery.

The specification '680 states:

Human lung carcinoma is classified into four principal histological types. That is, lung adenocarcinoma, squamous cell carcinoma, small cell carcinoma and large cell carcinoma. This invention relates to a monoclonal antibody having reactivity with human lung adenocarcinoma, to a glycoprotein antigen recognizable by this antibody and to a detection method and a therapeutic drug of human lung adenocarcinoma in which the monoclonal antibody is used. Also, this invention can be used in the diagnosis and treatment of human lung adenocarcinoma and is applicable to the field of diagnostic drugs and therapeutic drugs of lung adenocarcinoma.

It appears that the scope of the patented claim 4 relates only to the diagnosis of human lung adenocarcinoma. Further, the recitation of a diagnostically effective amount of said monoclonal antibody would be inherent in claim 4 because without a diagnostically effective amount of antibody, claim 4 would be inoperable.

Art Unit: 1642

6. The examiner suggests that the instant claim 12 be canceled and new claims drawn to immunoassays comprising the detection of the glycoprotein antigen in human secretions (page 14, lines 22-26) and detection of the glycoprotein antigen in human lung tissue (page 13, lines 14-18) be added in lieu of claim 12.

7. All other rejections and objections set forth in Paper no. 16 are withdrawn.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571)272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.

Art Unit 1642

Karen A. Canella
KAREN A. CANELLA PH.D.
PRIMARY EXAMINER